



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,291	01/08/2002	Christian John Cook	P67120US0	2439
136	7590	03/05/2004	EXAMINER	
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			LEVY, NEIL S	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,291

Applicant(s)

COOK, CHRISTIAN JOHN

Examiner

Neil Levy

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/03/03
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52, 55-59, 64, 67-84 & 93-98 is/are pending in the application.
- 4a) Of the above claim(s) 81-84, 94-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 52, 55-59, 64, 67-80 and 93 is/are allowed.
- 6) ☒ Claim(s) 52, 55-59, 64, 67-80 and 93 is/are rejected.
- 7) ☒ Claim(s) 59 is/are objected to.
- 8) ☒ Claim(s) 52, 55-59, 64, 67-84 & 93-98 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 81-84, 94-98 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claims 52, 58, 61, 64, 67-80, 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of 4/11/03 is maintained.

The compounds constituting the several structurally and functionally mentioned groups should be identified in the claim, in order to particularly claim this invention. As written, applicant wishes to claim an inordinate number of known and unknown compounds, minimally identified only as antagonists and as CRF antagonists, as antistress, not further elucidated, agents. Possibly only the CRF is the antagonist.

Claims 52, 58, 61, 64, 67-80, 93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim 52 recites an antistress agents. Stress, and antistress, are not further limited, as far as examiner, can determine, thus open to physical, chemical, psychological or physiological interpretation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factor are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction of guidance presented; (7) the presence of absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that instant disclosure fails to meet the enablement requirement for the following reasons;

(1) The nature of the invention: unidentified antistress agents as antagonists of structural and functional groups.

(2) The state of the prior art the use of these compounds for non-specific protection-experimentation was required.

(3) The relative skill of those in the art

The relative skill of those in the art is that of a skilled investigator.

(4) The predictability or unpredictability of the art

The unpredictability of the art is very high.

(5) The breadth of the claims

They are beyond attainment.

(6) The amount of direction or guidance presented.

(7) The presence or absence of working examples

There are no demonstrations of any of the criteria claimed.

(8) The quantity of experimentation necessary: extensive

The agent groups are of gross dimensions; thousands of pyridylpropanones can be envisioned, each to be tested in each of the modes of stress, each then to be tested by innumerable compounds, unidentified, as stress antagonists. Intense experimentation and overwhelming testing would need to be done to identify stress, stress antagonists of each of the 5 structural and functional groups. Applicant should identify the anti stress agents, at the very least, also the second agent, of the 8 groups of claim 58.

Claims 67-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of 4/11/03 is maintained, and expanded.

The "formulation" now claimed are not further defined-we do not know how much of which amino acid is in the formulation, not the ratio or amount of antistress agent, nor the animal-In essence, the formulation can not be determined without the animal, but the animal is not part of the formulation or composition; the claims appear to be method attempts, they are uninterpretable.

Claims 70-73, 75-78, 80 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection 4/11/03 is maintained.

As in the rejection of claim 52, above the functional component is open to wide interpretation and, absent claim to specific compounds, ambiguous. Claim 77 is rejected as it is unclear if the composition is the bolus, or is encapsulated within the bolus (or boluse?).

Claim 80 is unclear what combination is intended-a diluent and ?; and what is meant by independently-an encapsulated diluent separate from the amino acid/agent composition? In claim 55, what is 9-41? Please provide the structure, (as #).

Claims 52, 58, 61, 64, 67-69, 80 and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaefer et al 5728675.

The rejection of record is maintained.

Applicant now claims amino acid and an antistress agent which is an antagonist of pyridyl propanones-antiprogestins-etc.etc. – The electrolytes and amino acids of Schaefer can be seen as meeting the claimed limitations absent any specific identification of compounds constituting the instant agent. Tryptophan is serotenergic.

Claims 52, 55-57, 61, 67, 68, 80 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black Burn-WO 82/0041 in view of Walser-WO 95/30418 or Ito-et al 5937790, and D Aley et al '93.

The rejection of record is maintained.

Applicant's arguments filed 10/9/03 have been fully considered but they are not persuasive. Arguments have been considered, but rejections maintained in view of the claims to compositions and wide interpretation of stress, generally recognized.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 571-272-0619. The examiner can normally be reached on T-F from 7:00 a.m to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

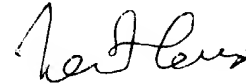
Art Unit: 1616

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Levy/tgd

February 25, 2004



NEIL S. LEVY
PRIMARY EXAMINER